

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

PATENT APPLICATION OF:	)	
	)	
NICOLAS PETER SHORTIS	)	Electronically filed on
	)	
U.S. SERIAL NO. 10/588,558	)	June 24, 2009
	)	
FILING DATE: August 4, 2006	)	
	)	
FOR: USE OF AMINOSALICYLATES IN	)	
DIARRHOEA-PREDOMINANT	)	
IRRITABLE BOWEL SYNDROME	)	
	)	
GROUP ART UNIT: 1614	)	
	)	
EXAMINER: Phyllis G. Spivack	)	
	)	
CUSTOMER NO. 23446	)	
	)	
CONFIRMATION NO. 8274	)	

**DECLARATION UNDER 37 C.F.R. § 1.131**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sirs:

I, Nicolas Peter Shortis, of Unit 6, 6-18 Bridge Road, Hornsby  
2077, New South Wales declare the following:

1. I am listed as the sole inventor of the subject matter disclosed and claimed in the subject patent application (hereafter the "Invention").

2. The subject application claims priority to an Australian application filed on February 6, 2004.

3. This Declaration is being provided to establish a date of conception and reduction to practice of the Invention in Australia on a date prior to September 25, 2003, which is the purported effective filing date of WO2005/030173 ("Wilson"), which was cited in a final Office Action mailed to the Applicant on March 11, 2009 in the subject application.

4. On a date prior to September 25, 2003, I conceived the Invention.

5. On a date prior to September 25, 2003 the Invention was successfully reduced to practice in Australia. Prior to September 25, 2003 I obtained some Balsalazide sold under the trade name Colazal from Salix Pharmaceuticals, Inc. of North Carolina USA. This Colazal contained Balsalazide and also a carrier compound. Prior to September 25, 2003 I treated a number of patients presenting with symptoms of Colitis. In some instances during this period patients were commenced on treatment with Balsalazide before the results of any colonoscopy to confirm the presence of Colitis. These patients responded well to treatment with Balsalazide. The colonoscopic results when they became available however showed the patient actually did not have Colitis at all but instead had diarrhoea predominant Irritable Bowel Syndrome (IBS). I

therefore determined that Balsalazide and its derivatives may also work in treatment and prophylaxis of diarrhoea predominant Irritable Bowel Syndrome (IBS) and other similar conditions. Having made this determination, I then administered Balsalazide to patients who previously had diarrhoea of unknown origin and patients with the diagnosis of diarrhoea predominant IBS. I administered Balsalazide to these patients prior to September 25, 2003. All patients responded well to Balsalazide with increasing doses (in other words, IBS was substantially or completely eradicated), confirming that the administration of Balsalazide was successful in the treatment and prophylaxis of irritable bowel syndrome.

6. To evidence reduction to practice of the Invention, attached hereto as Exhibits A and B are lab notebook pages dated prior to September 25, 2003 (the actual dates are blanked out) regarding a male patient approximately 38 years (information blanked out to protect his privacy). These notebooks came from my colleague Dr. Thomas Borody, a clinical gastroenterologist and medical director of Centre for Digestive Diseases, a clinic set up in Five Dock, Australia for treating patients with various gastrointestinal disorders. With reference to Exhibit A, Dr. Borody working under my direction and under strictest confidence met with a patient presenting with longstanding (approximately 2 to 3 years) low abdominal pain and diarrhoea with very loose stools. The notebook

shows that the patient was having motions up to seven times a day, mostly in the morning and with urgency. The patient had previously tried imodium without result. The patient was diagnosed with diarrhoea predominant irritable bowel syndrome. Having failed other medications, Dr. Borody discussed treatment with Colazide which I supplied freely to the patient. The patient was instructed to return fortnightly for follow-up. With reference to Exhibit B, on follow-up the patient was reviewed and there was a marked improvement in symptoms. The patient had experienced a significant drop in motions (2-3 times a day) and the motions were more like thick porridge. There was no urgency or pain and the patient was happy with the response. Dr. Borody made me aware of these results prior to September 25, 2003.

7. I certify that all statements made herein of my own knowledge are true, and that all statements made herein on information and belief are believed to be true. I understand that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. § 1001) and may jeopardize the validity of the application or any patent issuing thereon.



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Nicolas Peter Shortis

22 May 2009

DATE

Date Redacted

Patient Information  
Redacted

Longstanding  
lower abdominal pain  
& diarrhea - Vc stools  
2-3 y  
Cm & Joff -  
Recently worse -  
up to 7/d  
mostly in morning  
+ H. Colicky  
no blood  
Test - ve flex sup.?  
Has tried Simethicone  
(F) Ulcer. No Ca

Med - Nil

Atty - Nil

Δ Diarrhea - Prod. 188

PLAN EXPLAINED previous patient's response

Having failed other Rx.  
Prescribed Cefazolin - as per  
Mr. McK Shurtz (Required  
free sample)

FOL 160 700 160  
250 250 250

Cefazolin

J

Patient Information  
Redacted

Renew

\* Our California trial

Marked improvement

Điểm số  $\geq 80\%$  25/1

- more like March 1889

- No finger of

— No peer.

Happy 5th birthday.

— N. S. Sportis aware

*[Signature]*

✓ 40 360

Reverend my friend

A handwritten signature, possibly 'S', is written on lined paper. The signature is a single, continuous, stylized stroke that loops around and ends with a small hook.